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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/605,708	10/21/2003	Zhiyuan Gong	GLOF:007USD1	2707

32425 7590 03/10/2010

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ART UNIT	**PAPER NUMBER**
1632	

MAIL DATE	DELIVERY MODE
03/10/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/605,708	GONG ET AL.	
	Examiner	Art Unit	
	ANOOP SINGH	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 December 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,9-15,20,21,24,30-32 and 35-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 9-15, 20-21, 24, 30-32, 35-44 and 45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's arguments and declaration filed 12/11/2009 have been received and entered. Claims 1-3, 9-15, 20-21, 24, 30-32, 35-44 and 45 are pending in this application.

Election/Restrictions

Applicant's election of claims 1-16, 20-21, 29-32 and 35-41 in the reply filed on January 19, 2006 was acknowledged. The applicants elected muscle specific promoter for examination. It is noted claim 19 was directed to muscle specific promoter and therefore claim 19 was also rejoined with elected groups. It is noted that applicants have also amended previously withdrawn claim 24, which is also rejoined for the examination purposes to the extent it reads on elected invention. Applicant timely traversed the restriction/election requirement in the reply filed on 1/19/2006. Claims 1-3, 9-15, 20-21, 24, 30-32, 35-44 and 45 are currently under examination.

Oath/Declaration

The Gong declaration filed on December 11, 2009, is *not* sufficient to remove the availability of Hua et al (thesis submitted to Departments of Botany & Zoology, National University of Singapore, 1995/96, IDS, filed 9/17/09) references applied under 35 U.S.C. 103(a).

Withdrawn-Claim Rejections - 35 USC § 102

Claims 15, 20-21, 30, 32, 39, 42-44 and 45 were rejected under 35 U.S.C. 102(a) as being anticipated by Gong et al (Asia Pacific Bio Tech News, 1998, 2, 16, 280, IDS). The rejection is withdrawn in view of predating the invention by the 1.131 declaration filed on February 20, 2008.

Maintained-Claim Rejections - 35 USC § 103

Claims 1, 36-37, 39-40, 42-45, remains rejected under 35 U.S.C. 103(a) as being unpatentable over Higashijima et al (Dev Biol. 1997; 192(2): 289-99, IDS), Hua et at (thesis submitted to Departments of Botany & Zoology, National University of Singapore, 1995/96, IDS, filed 9/17/09) and Yanong et al (Seminars in Avian and Exotic Pet Medicine, October, Vol 5, No 4, 1996: 22-235) or Mulertt Hugo (The Goldfish and its systematic culture with a view of profit, 1883).

With respect to claims 43-45, Higashijima et al teach a method comprising obtaining transgenic fish by screening one or more transgenic zebrafish embryos comprising fluorescent gene under the control of a muscle specific promoter by exposing to a light source and selecting embryo showing stable fluorescence to produce transgenic line that shows EGFP throughout the body of one line whereas other two transgenic lines showed identical spatial expression of GFP in muscle cells (pp 295, col. 1, para 2, Fig 2, 4 and table 1, page 290, col. 2, last para.), demonstrating consistent expression of green fluorescence meeting the limitation of the claims. With respect to claim 36-37, 39-40, Higashijima et al teach that the fluorescent progeny (F1) of each founder were raised to sexual maturity and mated with wild-type fish. All the lines tested produced fluorescent embryos and level of expression was also completely inherited. Additionally, Higashijima et al show stable transmission of GFP expression in three lines of F3 generation suggesting that transgene is stably integrated into the genome of each zebra fish line (pp 297, col. 1, para. 1). It is also disclosed that fluorescence expression could be seen with FITC filter suggesting that fluorescent expression on fish could be best viewed at excitation wavelength of blue light (360-420 nm) (pp 292, col.2, para 2) . Higashijima et al do not teach distributing fish displaying green color to the ornamental fish market.

However, such was suggested by Hua who reported long term economic value of creating transgenic ornamental fish that express the green fluorescent protein in its muscle. It is noted that Hua et al also characterize the MLC 2 promoter, a fusion gene of the MLC promoter and contemplate driving the GFP expression in a fish. Additionally, Hua et al teach that GFP will be expressed only in the fast skeletal muscle. Hua et al further contemplate using the same gene construct to create other transgenic ornamental fishes (see page 81, last para. and page 82, para. 1). While Hua et al provide explicit motivation to crate a transgenic ornamental fish showing fluorescence that has a great economic value, but did not teach distributing ornamental fish to market.

However, distribution of ornamental fish to market was well known to one of ordinary skill in the art. For instance, Yanong disclosed that different variety of ornamental fish are sold at pet store or through mail order catalogue (see page 223, col. 1, para. 2). Mulertt Hugo also discloses ornamental fish such as gold fish are distributed in market and offered for sale in China (see page 6).

It would have been obvious for one of ordinary skill in the art at the time of invention to modify the method of Higashijima by providing fluorescent transgenic fish to ornamental fish market as described by Hua and Yanong/ Hugo. Higashijima et al had already disclosed a method for obtaining fluorescence transgenic fish displaying fluorescence in the muscle of the fish. In addition, Hua provided motivation by reporting long term economic value of creating transgenic ornamental fishes that express the green fluorescent protein gene in its muscle. Other limitations of claim 1, wherein fish displays color in sunlight would have been routine optimization of screening and selecting stable transgenic embryo using the method of Higashijima et al to select an embryo showing fluorescence in different light including sun light to generate stable transgenic line suitable. One who would have practiced the invention would have had reasonable expectation of successfully obtaining a transgenic fish comprising fluorescent gene and distributing in the market because Higashijima already taught a method for obtaining transgenic fish line that exhibits fluorescence on the muscle cells, while Hua taught long term economic value of creating transgenic ornamental fishes that express the green fluorescent protein gene in its muscle and also embraced the potential of using muscle specific MLC 2 promoter for driving the GFP expression in the fish that glows in the dark. One of ordinary skill in art would have been motivated to combine the teaching Higashijima, Hua and Yanong/ Hugo because a fluorescent transgenic fish comprising a fluorescent gene operably linked to a promoter would have allowed the artisan to distribute fluorescent fish displaying color at a place of normal or ordinary uses of such an item (pet store or ornamental fish market) for marketing the transgenic fish as per teaching of Yanong/ Hugo.

Therefore, the claimed invention would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention.

Claims 2-3 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Higashijima et al (Dev Biol. 1997; 192(2): 289-99, IDS), Hua et at (thesis submitted to Departments of Botany & Zoology, National University of Singapore, 1995/96, IDS), Yanong et al (Seminars in Avian and Exotic Pet Medicine, October, Vol 5, No 4, 1996: 22-235) or Mulertt Hugo (The Goldfish and its systematic culture with a view of profit, 1883) as applied to claims 1, 36-37, 39-40, 42-45 above, and further in view of Abeywickrama et al (US Patent no: 5028839, dated 7/2/1991).

The combined teachings of Higashijima et al, Hua et al and Yanong/ Hugo have been discussed above and relied in same manner here. While combination of reference teach viewing the transgenic fish under the blue light, but differ from claimed invention by not explicitly teaching displaying any fish under any other light source.

Prior to instant invention, use of fluorescent lamp in aquaria was well known to person of ordinary skill. Specifically, Abeywickrama et al teach fluorescent lamp including a luminescent layer comprising a mixture of red, green and blue phosphors,

each phosphor when the lamp is in use emitting light in a respective spectral region, the red phosphor emitting predominantly in the spectral region of from 610 nm to 620 nm, the green phosphor emitting predominantly in the spectral region of from 540 nm to 545 nm and the blue phosphor having a peak emission wavelength in the spectral region from 430 nm to 480 nm (see abstract and claim 3).

It would have been obvious for one of ordinary skill in the art at the time of invention to modify the method of Higashijima, Hua and Yanong/ Hugo et al by displaying the transgenic fluorescent fish under lamp emitting light in different spectra region in order to better visualize the fluorescence emitting fish. Higashijima provided motivation by indicating that different fluorescence gene have different emission spectra. It is noted that Higashijima, specifically viewed transgenic fish expressing GFP under fluorescent lamp (420-488nm). One who would have practiced the invention would have had reasonable expectation of successfully displaying the transgenic fish comprising fluorescent gene under light emitting different wavelength as disclosed by Abeywickrama for displaying fluorescent transgenic fish for ornamental purposes. One of ordinary skill in art would have been motivated to combine the teaching Higashijima, Hua, Yanong/ Hugo and Abeywickrama because a fluorescent transgenic fish comprising one or more fluorescent gene operably linked to a promoter displayed under lamp emitting light of different emission spectra would have provided fluorescent fish that would have attracted attention upon distribution of fluorescent transgenic fish as in a pet store or ornamental fish market for commercial sale as taught by Hua and Yanong/ Hugo.

Therefore, the claimed invention would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention.

Claim 21 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Higashijima et al (Dev Biol. 1997; 192(2): 289-99, IDS), Hua et at (thesis submitted to Departments of Botany & Zoology, National University of Singapore, 1995/96, IDS), Yanong et al (Seminars in Avian and Exotic Pet Medicine, October, Vol 5, No 4, 1996: 22-235) or Mulertt Hugo (The Goldfish and its systematic culture with a view of profit, 1883) as applied to claims 1, 36-37, 39-40, 42-45 above, and further in view of Moss et al (Gene. 1996; 173: 89-98, IDS).

The combined teachings of Higashijima et al, Hua, Yanong/ Hugo et al have been discussed above and relied in same manner here. Although, Higashijima taught a transgenic fish comprising fluorescent gene under control of muscle specific promoter and Hua embraced the potential of ML2 promoter to produce transgenic ornamental fish but combination of references differ from claimed invention by not expressing GFP under the control of MLC2 gene promoter.

Prior to instant invention, Moss et al. teach a zebrafish that comprises a myosin light chain enhancer operatively linked to a sequence encoding GFP for the muscle

specific expression. Characterization of the resulting fish indicated fluorescence from expression of the transgene was seen uniquely in the muscle and not other non-muscle cells in the fish.

It would have been obvious for one of ordinary skill in the art at the time of invention to modify the method of Higashijima to replace beta-actin promoter with functionally equivalent other muscle specific promoter such as MLC promoter that showed the specificity of expression in muscles of Zebrafish as per the teaching of Hua and Moss. One who would have practiced the invention would have had reasonable expectation of successfully modifying the construct disclosed by Higashijima to replace beta actin promoter with MLC2 promoter as Hua and Moss both taught that MLC promoter work well in zebrafish with specific expression in muscle cells of the fish. One of ordinary skill in art would have been motivated to combine the teaching Higashijima, Chan, Hua, Yanong/ Hugo because a fluorescent transgenic fish comprising one or more fluorescent gene operably linked to a muscle specific promoter such as MLC2 would have provided strong muscles specific fluorescence suitable for distribution of fluorescent transgenic fish to the pet store or ornamental fish market.)

Therefore, the claimed invention would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention.

Claim 20 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Higashijima et al (Dev Biol. 1997; 192(2): 289-99, IDS), Hua et at (thesis submitted to Departments of Botany & Zoology, National University of Singapore, 1995/96, IDS), Yanong et al (Seminars in Avian and Exotic Pet Medicine, October, Vol 5, No 4, 1996: 22-235) or Mulertt Hugo (The Goldfish and its systematic culture with a view of profit, 1883) as applied to claims 1, 36-37, 39-40, 42-45 above, and further in view of Liao et al (Analytical Biochemistry, 253, 1997, 137-139, IDS).

The combined teachings of Higashijima et al, Hua, Yanong/ Hugo et al have been discussed above and relied in same manner here. Although, Higashijima taught a transgenic fish comprising fluorescent gene under control of muscle specific promoter and Hua embraced the potential of ML2 promoter to produce transgenic ornamental fish but combination of references differ from claimed invention by not expressing GFP under the control of MCK promoter.

Prior to instant invention, Liao teaches successful isolation of a 4.3 kb promoter region from a zebrafish cytokeratin gene.

It would have been obvious for one of ordinary skill in the art at the time of invention to modify the method of Higashijima to substitute beta-actin promoter with other muscle specific promoter such as MCK as disclosed by Liao, as a matter of design choice, said design choice amounting to combining prior art elements according to known methods to yield predictable results. One who would have practiced the invention would have had reasonable expectation of successfully modifying the

construct disclosed by Higashijima to replace beta actin promoter with MCK promoter since Higashijima had already indicated that tissue specific promoter/enhancer from zebrafish origin work well in zebrafish (see page 290, col. 1, last para. bridging to col. 2, page 298, col. 2, para. 1). One of ordinary skill in art would have been motivated to combine the teaching Higashijima with Liao because a fluorescent transgenic fish comprising one or more fluorescent gene operably linked to a muscle specific promoter such as MCK would have provided strong muscles specific fluorescence for distribution of fluorescent ornamental transgenic fish to pet store or ornamental fish market.

Therefore, the claimed invention would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention.

Claim 38 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Higashijima et al (Dev Biol. 1997; 192(2): 289-99, IDS), Hua et at (thesis submitted to Departments of Botany & Zoology, National University of Singapore, 1995/96, IDS), Yanong et al (Seminars in Avian and Exotic Pet Medicine, October, Vol 5, No 4, 1996: 22-235) or Mulertt Hugo (The Goldfish and its systematic culture with a view of profit, 1883) as applied to claims 1, 36-37, 39-40, 42-45 above, and further in view of Culp et al (PNAS, 1991, 88, 7953-7957) .

The combined teachings of Higashijima et al, Hua, Yanong/ Hugo et al have been discussed above and relied in same manner here. Although, Higashijima taught a transgenic fish comprising fluorescent gene under control of muscle specific promoter and Hua embraced the potential of ML2 promoter to produce transgenic ornamental fish but combination of references differ from claimed invention by not disclosing breeding the first transgenic fish with a second transgenic fish of same specie.

However, prior to instant invention, it was routine to cross transgenic founder sibling or to a non transgenic wild type fish to generate stable transgenic fish. For instance Culp et al teach raising transgenic embryo to sexual maturity and then pair-mated to each other or to uninjected fish to generate stable transgenic zebra fish (see table 1 and page 7954, col. 2, para. 2).

Therefore, it would have been *prima facie* obvious for a person of ordinary skill in the art seeking to distribute ornamental fish displaying color to ornamental fish market by combining the respective teachings of Higashijima , Hua, Yanong/ Hugo and Culp to generate stable transgenic zebra fish line using the method disclosed by Culp, with a reasonable expectation of success. A person of skill in the art would have been motivated to cross the transgenic fish (F1) with a second fish that is either a wild type or a transgenic fish as disclosed by Culp et al, as a matter of design choice, said design choice amounting to combining prior art elements according to known methods to yield predictable results. One who would have practiced the invention would have had reasonable expectation of successfully obtaining a stable transgenic fish line comprising fluorescent gene and distributing in the market because Higashijima et al had already

disclosed a method for obtaining stable fluorescence transgenic fish line displaying fluorescence, while Hua, Yanong/ Hugo had described that distribution of ornamental fish for sale in fish in ornamental fish market. Given that prior art teaches that pair-mating of transgenic fish (F1) to each other or to wild type to generate stable transgenic line, it would have only required routine experimentation to combine the teaching of Higashijima , Hua, Yanong/ Hugo to generate stable transgenic line that expresses fluorescence on the surface of the fish up on exposure to a light. This would have allowed the artisan to distribute fluorescent fish displaying color to pet store or ornamental fish market.

Thus, the claimed invention, as a whole, is clearly *prima facie* obvious in the absence of evidence to the contrary.

Claim 41 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Higashijima et al (Dev Biol. 1997; 192(2): 289-99, IDS), Hua et at (thesis submitted to Departments of Botany & Zoology, National University of Singapore, 1995/96, IDS), Yanong et al (Seminars in Avian and Exotic Pet Medicine, October, Vol 5, No 4, 1996: 22-235) or Mulertt Hugo (The Goldfish and its systematic culture with a view of profit, 1883) as applied to claims 1, 36, 43 above, and further in view of Lin et al (US patent application no 20020178461, dated 4/30/2002 effective filing date 6/9/1997) or Hernández et al (Mol Mar Biol Biotechnol. 1997 Dec;6(4):364-75).

The combined teachings of Higashijima et al, Hua et al and Yanong/ Hugo have been discussed above and relied in same manner here. Higashijima taught a transgenic fish comprising fluorescent gene under control of muscle specific promoter, while Hua embraced the potential of ML2 promoter to produce transgenic ornamental fish of other species particularly the ornamental fish species by using the same gene construct to create other transgenic ornamental fishes (see page 82, para. 1 in Hua). However, combination of reference does teach making transgenic fish of other species.

However, such was known in prior art. For instance, Lin et al teaches that it was routine in art to make transgenic fish comprising an exogenous construct, wherein the construct comprises homologous expression sequences operably linked to a sequence encoding an expression product, wherein the expression product is expressed only in specific cell lineages, wherein the expression product is a GFP and wherein the fish is s selected from the group consisting of zebrafish, medaka, trout, salmon, carp, tilapia, goldfish, loach, and catfish (see claim 1, 4-5 and 7 and 26 and 28 of '461). Likewise, Hernández et al teach making stable transgenic tilapia line was routine in art (see abstract).

It would have been obvious for one of ordinary skill in the art at the time of invention to modify the method of Higashijima by substituting the embryo from zebrafish with functionally equivalent embryo from another specie of fish such as tilapia to generate stable transgenic tiapia fish line using the method known in prior art, with a

reasonable expectation of success. A person of skill in the art would have been motivated to do so in order to generate other species of ornamental fish as per the teaching of Hua for distribution to ornamental fish market, as a matter of design choice, said design choice amounting to combining prior art elements according to known methods to yield predictable results. One who would have practiced the invention would have had reasonable expectation of successfully obtaining a stable transgenic fish line of other species of fish comprising fluorescent gene and distributing said fish in the market because Higashijima et al, Lin/ Hernández et al and had already disclosed a method for obtaining stable transgenic fish of other species, while Hua, Yanong/ Hugo had described that distribution of ornamental fish for sale in fish in ornamental fish market. Given that prior art teaches that stable transgenic line of other species could be made, it would have only required routine experimentation to combine the respective teaching to generate stable transgenic line from different species. This would have allowed the artisan to distribute fluorescent fish displaying color to pet store or ornamental fish market.

Therefore, the claimed invention would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention.

Claims 9-11, 15, 24, 30-32, 35 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Higashijima et al (Dev Biol. 1997; 192(2): 289-99, IDS), Hua et at (thesis submitted to Departments of Botany & Zoology, National University of Singapore, 1995/96, IDS), Yanong et al (Seminars in Avian and Exotic Pet Medicine, October, Vol 5, No 4, 1996: 22-235) as applied to claims 1, 36-37, 39-40, 42-45 above, and further in view of Flanagan (Virus Genes, 1987, 1:61-71) and Chalfie, et al Green fluorescent protein: properties, applications, and protocols, Wiley-Liss, New York, 1998, art of record).

The combined teachings of Higashijima et al, Hua and Yanong have been discussed above and relied in same manner here. Higashijima et al teach a method comprising obtaining transgenic fish by screening one or more transgenic zebrafish embryo comprising fluorescent gene under the control of a muscle specific promoter by exposing to a light source and selecting embryo showing stable fluorescence to produce transgenic line that shows EGFP throughout the body of one line whereas other two transgenic lines showed identical spatial expression of GFP in muscle cells (pp 295, col. 1, para 2, Fig 2, 4 and table 1, page 290, col. 2, last para.). Higashijima et al report use of ubiquitous promoter to drive expression of reporter gene in transgenic fish (see page 290, col. 1, para. 1, see Lin and page 291, col. 2, last para., Amsterdam et), but differ wherein one or more gene is under the control of different promoters.

Such is disclosed by Flanagan who taught a recombinant plasmid comprising two different reporter genes in opposing direction, driven by two different promoters (see

Figure 1). Flanagan taught use of various promoters as the plasmid was used for the purpose of comparing the activity of different promoters by comparing the resulting reporter gene expression. Flanagan taught that divergent orientation of the promoters minimized any interference between the promoters (pages 67-70). Flanagan differs from claimed invention by not disclosing use of different fluorescent protein as reporter gene.

However, at the time the claimed invention was made, use of different fluorescent genes as reporter gene were available in prior art. Chalfie disclosed cloning of cDNA for green fluorescent protein (GFP) originally isolated from the jellyfish that is modified by site-directed mutagenesis for different emission spectra and thus several artificial fluorescent color proteins including yellow fluorescent protein (YFP), blue fluorescent protein (BFP), and cyan fluorescent protein (CFP) were available prior to instant invention (see pages 29-30, 244-246, especially pages 30 and 245, para 1 and 2). Chalfie differed from the claimed invention by not teaching expressing fluorescent gene in transgenic fish.

It would have been obvious for one of ordinary skill in the art at the time of invention to modify the method of Higashijima by providing fluorescent transgenic fish to ornamental fish market by substituting one fluorescent gene such as GFP with functionally equivalent other fluorescent gene such as BFP, YFP, as disclosed by Chalife. This would have allowed person of ordinary skill to express different fluorescent color for distribution of transgenic fish displaying different color for distribution. The limitation of claim 15, 24 32-33 directed to fish expressing one or more color because of different fluorescent protein under the control of distinct MLC2, alpha, beta-actin promoter and/or ubiquitous promoter thereby expressing fluorescence in different tissue would have been an obvious modification to one or ordinary skill in the art. It is relevant to point that Higashijima et al specifically taught a transgenic fish line comprising nucleic acid encoding fluorescence protein operably linked to alpha, beta-actin promoter and also reported use of *Xenopus* elongation factor 1alpha enhancer/promoter (see page 290, col. 1, para. 1), while Flanagan provided guidance with respect to use of plasmid comprising two different reporter genes in opposing direction, driven by two different promoters. One who would have practiced the invention would have had reasonable expectation of successfully obtaining a transgenic fish comprising one or more fluorescent gene under the control of muscle specific promoter and/or ubiquitous promoter because Higashijima already taught a method for making fluorescent transgenic fish. One of skill in the art would have a reasonable expectation of success in combining the above teachings as the molecular tool and technology was well known, routine and available at the time of filing that would have provided fluorescent fish that would have attracted attention upon distribution of color displaying transgenic fish in pet store or ornamental fish market.

Therefore, the claimed invention would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention.

Claims 11-14 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Higashijima et al (Dev Biol. 1997; 192(2): 289-99, IDS), Hua et at (thesis submitted to Departments of Botany & Zoology, National University of Singapore, 1995/96, IDS), Yanong et al (Seminars in Avian and Exotic Pet Medicine, October, Vol 5, No 4, 1996: 22-235) or Mulertt Hugo (The Goldfish and its systematic culture with a view of profit, 1883) as applied to claims 1, 36-37, 39-40, 42-45 above, and further in view of Yang et al (1998; 273(14):8212-6, IDS) and Living Colors Subcellular Localization Vectors (October 1998) CLONTECHniques XIII (4):8-9, art of record).

The combined teachings of Higashijima et al, Hua, Yanong/ Hugo have been discussed above and relied in same manner here. Although, combination of reference teaches obtaining a transgenic fish expressing GFP/EGFP, but differ from claimed invention by not disclosing expressing other fluorescent protein.

At the time the claimed invention was made, GFP and other variants of GFP were available in prior art. CLONTECHniques disclosed availability of enhanced cyan fluorescent protein (ECFP), an alternative to enhanced blue fluorescent protein and enhanced yellow fluorescent protein (EYFP) color variants (see page 8 and 9), while Yang et al taught to combine a blue emission mutant of GFP containing four point mutations (Phe-64 to Leu, Ser-65 to Thr, Tyr-66 to His, and Tyr-145 to Phe) with a synthetic gene sequence containing codons preferentially found in highly expressed human proteins to overcome the dim fluorescence and low expression levels attained in higher eukaryotes with such variants (see abstract).

It would have been obvious for one of ordinary skill in the art at the time of invention to modify the method of Higashijima by providing fluorescent transgenic fish to ornamental fish market by substituting one fluorescent gene such as GFP with functionally equivalent other fluorescent gene such as EYFP, ECFP as disclosed by Yang and CLONTECHniques as a matter of design choice, said design choice amounting to combining prior art elements according to known methods to yield predictable results. One who would have practiced the invention would have had reasonable expectation of successfully obtaining a stable transgenic fish line comprising fluorescent gene and distributing in the market because Higashijima et al had already disclosed a method for obtaining stable fluorescence transgenic fish line displaying fluorescence, while Hua, Yanong/ Hugo had described that distribution of ornamental fish for sale in fish in ornamental fish market. Hence it would have been prima facie obvious to combine the teaching Higashijima, Yang et al/ CLONTECHniques because a fluorescent ornamental transgenic fish comprising one or more fluorescent gene operably linked to a promoter would have provided fluorescent fish showing multiple colors and thereby suitable for distribution to pet store or ornamental fish market.

Therefore, the claimed invention would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention.

Claims 1, 36-37, 39-40, 42-44 and 45 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Higashijima et al (Dev Biol. 1997; 192(2): 289-99, IDS) and Yanong et al (Seminars in Avian and Exotic Pet Medicine, October, Vol 5, No 4, 1996: 22-235).

Claims 1, 36-37, 39-40, 42-45, are included in the rejection to the extent base claim is interpreted broadly reading on obtaining a transgenic zebra fish line expressing GFP and distributing said fish to ornamental fish market. For the purpose of instant rejection, the term ornamental is interpreted broadly in view of applicant's disclosure that does not appear to be limited to ornamental species of fish per se and embrace a general list of different kind of fish. While there are some species listed may be considered ornamental, some are clearly not ornamental. Moreover, it is noted that the listing includes the recitation of "etc." (see para. 96, page 47 of the specification). Therefore, without any clear indication of the specificity of the listing any fish displaying color is considered ornamental fish suitable for sale in ornamental fish market.

With respect to claims 43-45, Higashijima et al teach a method comprising obtaining transgenic fish by screening one or more transgenic zebrafish embryos comprising fluorescent gene under the control of a muscle specific promoter by exposing to a light source and selecting embryo showing stable fluorescence to produce transgenic line that shows EGFP throughout the body of one line whereas other two transgenic lines showed identical spatial expression of GFP in muscle cells (pp 295, col. 1, para 2, Fig 2, 4 and table 1, page 290, col. 2, last para.), demonstrating consistent expression of green fluorescence meeting the limitation of the claims. With respect to claim 36-37, 39-40, Higashijima et al teach that the fluorescent progeny (F1) of each founder were raised to sexual maturity and mated with wild-type fish. All the lines tested produced fluorescent embryos and level of expression was also completely inherited. Additionally, Higashijima et al show stable transmission of GFP expression in three lines of F3 generation suggesting that transgene is stably integrated into the genome of each zebra fish line (pp 297, col. 1, para. 1). It is also disclosed that fluorescence expression could be seen with FITC filter suggesting that fluorescent expression on fish could be best viewed at excitation wavelength of blue light (360-420 nm) (pp 292, col.2, para 2) . Higashijima et al differ from claimed invention by not explicitly teaching distribution of ornamental fish displaying color to ornamental fish market.

However, distribution of ornamental fish to market was well known to one of ordinary skill in the art. For instance, Yanong teaches that different varieties of ornamental fish are sold at pet store or through mail order catalogue (see page 223, col. 1, para. 2).

It would have been obvious for one of ordinary skill in the art at the time of invention to combine the respective teaching by providing fluorescent transgenic fish of Higashijima to ornamental fish market to sell the transgenic ornamental fish as disclosed by Yanong. A person of skill in the art would have been motivated to do so

because Yanong taught that coloration of fish is an important trait of ornamental fish. Given that Higashijima et al had already disclosed a method for providing transgenic fish displaying fluorescence in the muscle of the fish. It would have been prima facie obvious for one of ordinary skill in the art to distribute the ornamental fish of Higashijima et al. Other limitations of claim 1, wherein fish displays color in sunlight would have been routine optimization of screening and selecting stable transgenic embryo using the method of Higashijima et al to select an embryo showing fluorescence in different light including sun light to generate stable transgenic line suitable for ornamental fish market. One who would have practiced the invention would have had reasonable expectation of successfully obtaining a transgenic fish comprising fluorescent gene and distributing in the market because Higashijima already taught a method for obtaining transgenic fish line, while Yanong had taught fish displaying is important trait of ornamental fish that could be sold in ornamental fish market. One of ordinary skill in art would have been motivated to combine the teaching Higashijima and Yanong because a fluorescent transgenic fish comprising a fluorescent gene operably linked to a promoter would have allowed the artisan to distribute fluorescent fish displaying color at a place of normal or ordinary uses of such an item such as pet store or ornamental fish market as per teaching of Yanong.

Therefore, the claimed invention would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention.

Response to arguments

1. Rejections that rely upon the Hua thesis, document C89

Applicants noted the entry of 8 separate obviousness rejections involving various combinations of references rejecting each of the pending claims. Each of these eight rejections relies principally on the Hua thesis, IDS document C89. Applicants argue that office action fails to show that the Hua thesis to be sufficiently "publicly accessible" to constitute a printed publication. Applicants cite multiple case laws to argue that Hua reference was not "publicly available". Applicants cite the Gong declaration to observe that Hua et al was students in his laboratory enrolled in the Undergraduate Honors Program (see para. 3 of the Gong declaration). It is further disclosed that copies of some of undergraduate thesis reports were at one time kept in a departmental reading room in the 1998 time frame (see para. 4 of the Gong declaration). The declaration concludes by noting again that Hua worked under his direction and control on a project that he (Dr. Gong) designed and implemented, and that a copy of each of documents

C89 and C90 was retained in his personal files. Additionally, Dr. Gong confirms that neither document C89 nor C90 are listed in the library card catalogue, nor the document could be found in the library (see page 5 and 6 of the arguments). Applicants' arguments have been fully considered, but are not found persuasive.

In response, it should be noted that applicants submitted the Hua reference as part of IDS for consideration that was submitted in 1995/1996 to Department of Botany and Zoology of National University of Singapore. The Gong declaration filed on 12/11/2009, itself provides evidence that the thesis in question at one point in time was accessible to departmental personnel in the reading room/departmental library. Absent evidence to the contrary, it is reasonable presumed that that Hua thesis was available after submission of thesis in 1995/1996. The burden is on applicants to provide evidence that thesis submitted in 1995/96 was not available in the departmental library/reading room prior to filing of instant application.

MPEP 2128.02 states "Evidence showing routine business practices can be used to establish the date on which a publication became accessible to the public. ..Court held that evidence submitted by Intel regarding undated specification sheets showing how the company usually treated such specification sheets was enough to show that the sheets were accessible by the public before the critical date.); In re Hall, 781 F.2d 897, 228 USPQ 453 (Fed. Cir. 1986) (Librarian's affidavit establishing normal time frame and practice for indexing, cataloging and shelving doctoral theses established that the thesis in question would have been accessible by the public before the critical date.). In the instant case, applicants' have submitted declaration by Dr. Gong, who is not directly responsible for handling the thesis in question for the department of Biological Science. It should be noted that the Gong's declaration states that copies of some of undergraduate thesis reports were at one time kept in a departmental reading room in the 1998 time frame. It is not apparent from the declaration if thesis submitted in 1995/1996 were accessible prior to 1998. Applicants have not provided affidavit from appropriate person responsible for handling the undergraduate thesis for the department reading room/library and establishing normal time frame and practice for indexing, cataloging and shelving thesis in question.

Higashijima et al and Yanong et al

Applicants disagree with the rejection of claims and assert that the action fails to set forth a *prima facie* rejection, noting that nowhere does any cited reference, that we can identify, teaches or suggests the preparation of fluorescent transgenic zebrafish capable of expressing the fluorescence gene at level sufficient such that said transgenic fish fluoresces upon exposure to sunlight, wherein said transgenic fish are offspring of an embryo line …wherein transgenic founders of said line fluoresce upon exposure to sunlight. Applicants submit the email exchange with Dr. Okamato showing the fish disclosed by Higashijima did not fluorescence under sunlight (see page 6 and 7 of the argument). Applicants assert that the examiner has previously withdrawn rejection based upon the email exchange.

Such is not persuasive, because as an initial matter applicant should note that independent claim claims 43, 36-37, 39-40, 42, 44-45 are not limited to generating transgenic fish showing fluorescence under any specific light.

With respect to claim 1, the previously withdrawn rejection of Higashijima et al has been reinstated because applicants subsequent to withdrawal of obviousness rejection on record have filed the declaration by Dr. Gong stating: " [b]ased on my knowledge and experience in the production of fluorescent, transgenic fish, it is my opinion that virtually any muscle-specific promoter can be employed to produce very highly fluorescent founder embryos and lines" (see Gong Declaration, para. 6, and argument, dated 10/7/2008). In addition, applicants have also made on record that "With respect to muscle promoters in general, which are admittedly well known in the art (copy enclosed as Exhibit 1). Dr. Gong addressed a number of items in his declaration relevant to the present appeal…. Dr. Gong addresses the question of the use of other muscle promoters to produce transgenic fish that express fluorescence that is visibly detectable, and explains generally why the generation of such transgenic fish, even when employing a relatively weak promoter, does not require an undue amount of experimentation (see applicants appeal filed 5/26/2009, page 5, para. 2)". In view of foregoing, it is clear that one of ordinary skill in the art practicing method of Higashijima would select an embryo that may be rare but predictable based on the screening assay

that should yield the desired characteristic of displaying color on the muscle surface of the fish irrespective of promoter and source of light used for generating transgenic fish for the distribution to ornamental fish market.

Additionally, the email exchange with Dr. Okamato showing the fish disclosed by Higashijima do not look green under sunlight (see page 6 and 7 of the argument) is not conclusive. The email exchange merely states “Our alfa-actin GFP fish do not look green under the day light as your fish do” does not support applicants’ position. The recitation of "do not look green under sunlight as your fish do" could be interpreted as fish disclosed by Higashijima show some color under sunlight that may not be as green as the fish disclosed by Gong. Furthermore, these assertions are not supported by any experimental evidence nor applicants have provided the statement in the form of declaration. MPEP 716.01(c) states" Objective evidence which must be factually supported by an appropriate affidavit or declaration to be of probative value includes evidence of unexpected results, commercial success, solution of a long-felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant. See, for example, *In re De Blauwe*, 736 F.2d 699, 705, 222 USPQ 191, 196 (Fed. Cir. 1984). In the instant case, there is no evidence on record that fish disclosed by Higashijima would not show the desired characteristics for distribution to ornamental fish market. One of ordinary skill in the art would be motivated to perform extensive screening of embryos for desired characteristics. Further, applicants’ arguments does not negate the fact that one of ordinary skill in the art could use the same method of screening to select an embryo showing stronger and higher fluorescence than one disclosed by Higashijima to generate transgenic fish. It should be noted that Higashijima et al teach a method of obtaining transgenic zebrafish showing fluorescence under a light said method comprising obtaining transgenic fish embryo comprising fluorescent gene under the control of a muscle specific promoter. The method disclosed by Higashijima et al comprises selection of embryo by exposing embryo under a light source, which is part of sunlight.

Regarding selection of GFP expressing embryo under sunlight, it is noted that prior art of Yanong et al generally recognized that "coloration is an important trait of ornamental fish." Yanong et al also disclose that "[m]ost natural color enhancers include carotenoids, sources of red, orange, and yellow colors in fish" (see page 227, col. 2, para. 1). In view of forgoing, it would have been obvious to one of ordinary skill in the art to select embryo showing strong fluorescence driven by muscle specific promoter under any light including natural light because selection of transgenic embryo (blue or visible) showing strong fluorescence would implicitly show fluorescence under all other lights including natural sunlight, as coloration was considered an important trait for ornamental fish in ornamental fish market.

Applicants separately argue that Yanong reference is of little relevance to the rejection with respect to claim 43 (and claims depending therefrom). Applicants argue that Yanong appears to discuss coloration in the context of good fish nutrition. Applicants assert that Yanong et al cannot be combined with the fish of Higashijima that is not colorful under sunlight (see applicants' argument pages 8 and 9).

Such is not persuasive because Yanong et al is cited to demonstrate that different varieties of ornamental fish are sold at pet store or through mail order catalogue (see page 223, col. 1, para. 2) and one ordinary skill in art would recognize that fish showing color under a light could be purchased from pet store (see for instance online catalogue of Pet mart at www.**petsmart**.com for ornamental fish, citation not relied for the rejection). Applicants' selective reading of Yanong et al ignores the teachings that coloration is an important trait of ornamental fish and such fish are routinely purchased from pet mart. These assertions of Yanong et al suggest that fish displaying color on the surface were routinely distributed and were available at local pet mart.

Applicants' argument that fish of Higashijima does not show color under sunlight is not persuasive for the reasons discussed above. As stated before, the email exchanges are not supported by any experimental evidence nor have applicants provided the statement in the form of declaration. The one line email statement neither conclusive nor clear, therefore, rejection of record is maintained for the reasons of

record. In the instant case, it would have been obvious for one of ordinary skill in the art at the time of invention to modify the method of Higashijima by providing fluorescent transgenic fish to fish market as described by Yanong et al. Higashijima et al had already disclosed a method for making fluorescence transgenic fish displaying fluorescence in the muscle of the fish. In addition, Yanong et al had described coloration of fish is an important trait for an ornamental fish that could be distributed in the pets mart (supra). It is noted that obviousness does not require absolute predictability of success; for obviousness under 35 U.S.C. § 103, all that is required is a reasonable expectation of success. See In re O'Farrell, 7 USPQ2d 1673 (CAFC 1988). One who would have practiced the invention would have had reasonable expectation of successfully obtaining a transgenic fish comprising fluorescent gene and distributing in the market because Higashijima already taught a method for obtaining transgenic fish line, while Yanong et al had taught fish displaying colors could be distributed to market.

Therefore, the claimed invention would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention.

Maintained-Double Patenting

Claims 1-3, 9-15, 20-21, 24, 30-32, 35-44 and 45 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 42-46, 53-55, 58-60, 63-65, 68-81 of copending Application No. 11/749032.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to a method of providing transgenic fish to ornamental fish market. For instance, instant claims 43-45 , 1-3, 9-15 are directed to a method of providing transgenic fish to the ornamental fish market comprising the step of (a) obtaining a transgenic ornamental fish comprising a chimeric gene comprising a promoter that drives the expression of a fluorescent protein selected from a group consisting of BFP, YFP and CFP predominantly in muscles of said fish, said promoter being a muscle specific promoter, such that said transgenic fish expresses fluorescent protein encoded by fluorescent gene in skeletal muscle at a level sufficient such that said transgenic fish fluoresces upon exposure to one or more light and (b) distributing said fish to the ornamental fish market. Subsequent claims limit the promoter to include MCK (claim 20) and MLC (claim 21). Claims also limit the method of claims to further comprises displaying fish under blue or UV light and wherein fish

expresses BFP (claim 9), EBFP (claim 10), YFP or other fluorescent gene set forth in claims 12-14. Claims are also directed to a method wherein the transgenic fish is stable transgenic fish line by breeding the transgenic fish with a second fish to obtain offspring, subsequently limiting the second fish to be selected form a list consisting of different species of fish (claim 36-42). In contrast, claims 42-46, 53-55, 58-60, 63-65, 68-81 of '032 are directed to a method of providing transgenic fish to the ornamental fish market comprising the steps of, obtaining transgenic fish embryos or fry comprising one or more fluorescence genes, wherein the transgenic fish embryos or fry express a fluorescent proteins encoded by the one or more fluorescence genes; (b) selecting one or more of from-said transgenic fish embryos or fry by exposing the embryos or fry to a light source one, (c) producing one or more transgenic lines of fish from said one or more selected embryos or fry; and (d) distributing transgenic fish produced from one or more of said selected lines to the ornamental fish market (claim 42). Subsequent claims limit the method, wherein said fish is displayed under blue or UV light (claim 43-44, 79 and 80), and expresses a GFP (claim 45). Claims 53-55, 58 limits the method of claim 42, wherein the promoter is zebrafish muscle specific promoter, further limiting to MLC promoter (claim 60). Claims 68-70, limit the method, wherein one or more fluorescent protein is expressed. Claims 71-80 limit the method of claim 42, wherein transgenic fish line is a stable transgenic line. Thus, the claims of instant application encompass the method specifically claimed in application '032.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Response to the argument

While Applicant has requested that the rejection be held in abeyance until allowable subject matter can be identified, a request of abeyance does not overcome or address an issue of obvious double patenting between claims 1-3, 9-15, 20-21, 24, 30-32, 35-44 and 45 in the instant case and application 10/749032. Thus the rejection is maintained.

Withdrawn-Double Patenting

Claims 1-3, 9-16, 19-21, 24, 30-32, 35-42 were rejected and newly added claims 43-45 are also rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 of U. S. Patent No. 7,135,613 in view of Higashijima et al (Dev Biol. 1997; 192(2): 289-99, IDS) and Yanong et al (Seminars in Avian and Exotic Pet Medicine, October, Vol 5, No 4, 1996: 22-235). Applicants have requested to change the relationship of instant application from continuation to divisional from '613 patent in order to overcome the rejection of record.

Conclusion

No claims allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Mulertt Hugo (The Goldfish and its systematic culture with a view of profit, 1883).

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANOOP SINGH whose telephone number is (571)272-3306. The examiner can normally be reached on 9:00AM-5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272- 4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Deborah Crouch/
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